Pressure ulcers

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ABSTRACT

INTRODUCTION: Unrelieved pressure or friction of the skin, particularly over bony prominences, can lead to pressure ulcers in up to a third of people in hospitals or community care, and a fifth of nursing home residents. Pressure ulcers are more likely in people with reduced mobility and poor skin condition, such as older people or those with vascular disease. METHODS AND OUTCOMES: We conducted a systematic review and aimed to answer the following clinical questions: What are the effects of preventive interventions in people at risk of developing pressure ulcers? What are the effects of treatments in people with pressure ulcers? We searched: Medline, Embase, The Cochrane Library and other important databases up to February 2007 (BMJ Clinical Evidence reviews are updated periodically, please check our website for the most up-to-date version of this review). We included harms alerts from relevant organisations such as the US Food and Drug Administration (FDA) and the UK Medicines and Healthcare products Regulatory Agency (MHRA). RESULTS: We found 60 systematic reviews, RCTs, or observational studies that met our inclusion criteria. We performed a GRADE evaluation of the quality of evidence for interventions. CONCLUSIONS: In this systematic review we present information relating to the effectiveness and safety of the following interventions: air-filled vinyl boots, air-fluidised supports, alternating pressure surfaces (including mattresses), alternative foam mattresses, constant low-pressure supports, debridement, electric profiling beds, electrotherapy, hydrocellular heel supports, low-air-loss beds (including hydrotherapy beds), low-level laser therapy, low-tech constant low-pressure supports, medical sheepskin overlays, nutritional supplements, orthopaedic wool padding, pressure-relieving overlays on operating tables, pressure-relieving surfaces, repositioning (regular "turning"), seat cushions, standard beds, standard care, standard foam mattresses, standard tables, surgery, therapeutic ultrasound, topical lotions and dressings, topical negative pressure, and topical phenytoin.

QUESTIONS

INTERVENTIONS

PREVENTIVE INTERVENTIONS FOR PRESSURE ULCERS

Beneficial

Likely to be beneficial

Unknown effectiveness

Unlikely to be beneficial

TREATMENTS FOR PRESSURE ULCERS

Likely to be beneficial

Unknown effectiveness

Key points

- Unrelieved pressure or friction of the skin, particularly over bony prominences, can lead to pressure ulcers, which affect up to a third of people in hospitals or community care, and a fifth of nursing-home residents.

  Pressure ulcers are more likely in people with reduced mobility and poor skin condition, such as older people or those with vascular disease.

- Alternative foam mattresses (such as viscoelastic foam) reduce the incidence of pressure ulcers in people at risk compared with standard hospital foam mattresses, although we don't know which is the best alternative to use.

  Low-air-loss beds may reduce the risk of pressure ulcers compared with standard intensive-care beds, but we don't know whether pressure-relieving overlays on operating tables are also beneficial compared with other pressure-relieving surfaces.

  Medical sheepskin overlays may reduce the risk of pressure ulcers compared with standard care.

- Hydrocellular heel supports may decrease the risk of pressure ulcers compared with orthopaedic wool padding, but air-filled vinyl boots with foot cradles and low-air-loss hydrotherapy beds may increase the risk of ulcers compared with other pressure-relieving surfaces.

  We don't know if other physical interventions, such as alternating pressure surfaces, seat cushions, electric profiling beds, low-tech constant low pressure supports, repositioning, or topical lotions and dressings are effective for preventing pressure ulcers. We also don't know whether pressure ulcers can be prevented by use of nutritional interventions.

- In people with pressure ulcers, air-fluidised supports may improve healing compared with standard care, although they can make it harder for people to get in and out of bed independently.

- Hydrocolloid dressings may also improve healing rates compared with standard dressings.

- We don't know whether healing is improved in people with pressure ulcers by use of other treatments such as alternating pressure surfaces, debriding agents, low-tech constant low pressure supports, low-air-loss beds, seat cushions, dressings other than hydrocolloid, topical phenytoin, surgery, electrotherapy, ultrasound, low level laser therapy, topical negative pressure, or nutritional interventions.

DEFINITION

Pressure ulcers (also known as pressure sores, bed sores, and decubitus ulcers) may present as persistently hyperaemic, blistered, broken, or necrotic skin, and may extend to underlying structures, including muscle and bone. Pressure ulcers are usually graded on a scale of 1 to 4, with a higher grade indicating greater ulcer severity. [1]

INCIDENCE/ PREVALENCE

Reported prevalence rates range from 4.7–32.1% for hospital populations, 4.4–33.0% for community-care populations, and 4.6–20.7% for nursing-home populations. [2]

AETIOLOGY/ RISK FACTORS

Pressure ulcers are caused by unrelieved pressure, shear, or friction. They are most common below the waist and at bony prominences, such as the sacrum, heels, and hips. They occur in all healthcare settings. Increased age, reduced mobility, impaired nutrition, vascular disease, faecal incontinence, and skin condition at baseline consistently emerge as risk factors. [3] [4] However, the relative importance of these and other factors is uncertain.

PROGNOSIS

There are little data on prognosis of untreated pressure ulcers. The presence of pressure ulcers has been associated with a two- to fourfold increased risk of death in elderly people and people in intensive care. [5] [6] However, pressure ulcers are a marker for underlying disease severity and other comorbidities, rather than an independent predictor of mortality. [5]

AIMS OF INTERVENTION

To prevent formation of a pressure ulcer; heal existing pressure ulcers; and improve quality of life, with minimal adverse effects of treatment.

OUTCOMES

Incidence and severity of pressure ulcers; rate of change of area and volume; time to heal; and adverse effects of treatment. Interface pressure recorded at various anatomical sites is a surrogate outcome that is sometimes used in studies of preventive interventions, but has not yet been linked to clinical outcomes.

METHODS

BMJ Clinical Evidence search and appraisal February 2007. The following databases were used to identify studies for this systematic review: Medline 1966 to February 2007, Embase 1980 to February 2007, and The Cochrane Library (all databases) 2007, Issue 1. Additional searches were carried out using these websites: NHS Centre for Reviews and Dissemination (CRD) — all databases, Turning Research into Practice (TRIP), and NICE. Abstracts of the studies retrieved from the initial search were assessed by an information specialist. Selected studies were then sent to the author for additional assessment, using pre-determined criteria to identify relevant studies.

Study-design criteria for inclusion in this review were: published systematic reviews and RCTs in any language, with any level of blinding, and containing any number of individuals, with any level of loss to follow-up. There was no minimum length of follow-up required to include studies. We included studies described as "open", "open label", and not blinded. In addition, we use a regular surveillance protocol to capture harms alerts from organisations such as the FDA and the UK Medicines and Healthcare products Regulatory Agency (MHRA), which are added to the reviews as required. We reviewed all RCTs that used objective clinical outcome measures. For many trials we could not be sure that the size of pressure ulcers was distributed evenly between groups at baseline. Unequal distribution of wound size at baseline would have an impact on all measures of wound healing. Ideally, studies of treatment should stratify randomisation by initial wound area and include enough participants to ensure even distribution of baseline wound size. A further difficulty in assessing the trials of pressure-ulcer prevention and treatment is that it can be difficult to determine from reports whether an RCT of a new device, for example a mattress, is sufficiently similar to be assessed with previously described mattresses, or whether it constitutes a new device. It can therefore be difficult to combine data from RCTs and assess overall effects of treatment options. We have performed a GRADE evaluation of the quality of evidence for interventions included in this review (see table, p 22).

QUESTION What are the effects of preventive interventions in people at risk of developing pressure ulcers?

OPTION FOAM ALTERNATIVES VERSUS STANDARD FOAM MATTRESSES TO PREVENT PRESSURE ULCERS

Incidence of pressure ulcers

Compared with standard hospital mattresses Foam alternatives may be more effective at 10–14 days at reducing the incidence of pressure ulcers in people at high risk of developing pressure ulcers (low-quality evidence).

Compared with each other Foam and fibre replacement mattresses consisting of five sections may be more effective than a 4-inch thick dimpled foam mattress at reducing the risk of pressure ulcers (low-quality evidence).

Foam alternatives or standard mattress plus different repositioning frequencies compared with standard care Combination of a viscoelastic foam mattress and 4-hourly repositioning may be more effective at reducing the incidence of pressure ulcers (very low-quality evidence).

For GRADE evaluation of interventions for pressure ulcers, see table, p 22 .

Benefits:

We found two systematic reviews (search dates 2004 [7] and 2006 [8]). The second systematic review [8] did not report outcomes data for included RCTs or perform a meta-analysis. Instead, it gave a narrative summary of results. We have therefore reported meta-analysis results from the earlier review. [7]

Foam alternatives versus standard hospital mattress:

Both reviews identified the same six RCTs (2117 people in hospital). [7] [8] Five RCTs identified by the reviews compared foam alternatives versus a standard hospital mattress, primarily in elderly people in orthopaedic hospital wards. The first review found that foam alternatives to the standard hospital mattress significantly reduced the incidence of pressure ulcers over 10–14 days (5 RCTs, 2016 people: RR 0.40, 95% CI 0.21 to 0.74). [7] The sixth RCT (101 people in the emergency room and after admission to hospital with hip fracture) identified by the reviews compared foam mattresses (viscoelastic foam mattress in the emergency room followed by a viscoelastic foam overlay on top of a standard mattress) versus standard mattresses (standard trolley mattress in the emergency room followed by a standard hospital foam mattress), and found no significant difference between mattress types in the incidence of pressure ulcers up to 14 days (people who developed a pressure ulcer: 4/48 [8%] with foam mattress *v* 8/53 [15%] with standard mattress; reported as not significant, P value not reported). [7] The second review reached similar conclusions (data and significance not reported). [8]

Different foam alternatives versus each other:

The reviews identified five RCTs (795 people) that compared different foam alternatives. [7] [8] One RCT (40 people) found that a foam and fibre replacement mattress consisting of five sections significantly reduced the risk of pressure ulcers compared with a 4-inch (10 cm) thick dimpled foam mattress (RR for development of pressure ulcer 0.42, 95% CI 0.18 to 0.96; NNT for 10–21 days' treatment 3, 95% CI 2 to 25). [7] The other RCTs were too small to detect a difference between the foam alternatives, because few people in the trials developed pressure ulcers. [7]

Foam alternatives or standard mattress combined with different repositioning frequencies: See benefits of repositioning, p 8 .

Harms: The reviews gave no information on adverse effects. [7] [8]

Foam alternatives or standard mattress combined with different repositioning frequencies: See harms of repositioning (including regular "turning") to prevent pressure ulcers, p 8 .

Comment: Most RCTs were small and of poor quality, and few performed the same comparison. Alternative foam mattresses consisted of foam of varying densities, often within the same mattress, and some were sculptured.

OPTION PRESSURE-RELIEVING OVERLAYS ON OPERATING TABLES TO PREVENT PRESSURE ULCERS

Incidence of pressure ulcers
Compared with standard table alone We don't know whether pressure-relieving overlays are more effective at reducing the incidence of pressures ulcers postoperatively (very low-quality evidence).

For GRADE evaluation of interventions for pressure ulcers, see table, p 22 .

Benefits: We found two systematic reviews (search dates 2004, 4 RCTs [7] and 2006, 5 RCTs, 4 of which were included in the first review [8]). The second systematic review [8] did not report outcomes data for included RCTs, or perform a meta-analysis. Instead, it gave a narrative summary of results. We have therefore reported meta-analysis results from the earlier review, [7] and have reported the further RCT identified by the second review separately.The first review meta-analysed results from two RCTs (368 people), and found that an alternating-pressure overlay, used during surgery and for 7 days postoperatively, significantly reduced the incidence of pressure ulcers over 7 days compared with a gel pad used during surgery plus a standard mattress used for 7 days postoperatively (RR 0.21, 95% CI 0.06 to 0.70; NNT for 7 days' treatment 16, 95% 9 to 48). Whether the reduced incidence of pressure ulcers was due to intraoperative or postoperative pressure relief, or both, is unclear. [7] The third RCT (446 people who had had elective major general, gynaecological, or vascular surgery) identified by the reviews found that a pressure-relieving viscoelastic polymer pad significantly reduced the incidence of postoperative pressure ulcers after 8 days compared with a standard table alone (RR 0.53, 95% CI 0.33 to 0.85; NNT for intraoperative use 11, 95% CI 6 to 36). [7] The fourth RCT (413 people) identified by the reviews compared an experimental foam overlay in the operating room versus standard care (the latter including standard pressure relief) and found that more people with an overlay had ulcers of grade 2 or worse than people having standard care (6/206 [3%] with overlay *v* 3/207 [1%] with standard care; significance assessment not performed). [7] The additonal RCT (175 people undergoing cardiac surgery) [9] identified by the second review [8] compared a thermoactive 4 cm viscoelastic foam overlay plus standard operating table (with water-filled warming mattress) versus a standard operating table alone. The RCT found no significant difference in the proportion of people who developed pressure ulcers postoperatively between overlays and standard operating tables alone, although more people using overlays developed sores (18% with overlay plus standard operating table *v* 11% with standard operating table alone; absolute numbers not reported; P = 0.22). [9]

Harms: The reviews [7] [8] and the RCT identified by the second review [9] gave no information on adverse effects.

Comment: Some of the RCTs were small and most were of poor quality; few performed the same comparison.

OPTION LOW-AIR-LOSS BEDS TO PREVENT PRESSURE ULCERS

Incidence of pressure ulcers
Low-air-loss beds compared with standard intensive-care beds/alternating-pressure mattresses We don't know whether low-air-loss beds are more effective at reducing the development of pressure ulcers (very low-quality evidence).

For GRADE evaluation of interventions for pressure ulcers, see table, p 22 .

Benefits: We found two systematic reviews (search dates 2004 [7] and 2006 [8]). The second systematic review did not report outcomes data for included RCTs or perform a meta-analysis. [8] Instead, it gave a narrative summary of results. We have therefore reported results from the earlier review, [7] and have reported the further RCT identified by the second review separately. The first review found that low-air-loss beds in intensive care significantly reduced the risk of new pressure ulcers compared with standard intensive-care beds (1 RCT, 98 people, duration of trial not reported; RR 0.24, 95%

CI 0.11 to 0.53; NNT 3, 95% CI 2 to 5). [7] One further RCT (62 people) identified by the second review [8] found no significant difference in the proportion of people who developed pressure ulcers between low-air-loss beds and an alternating-pressure mattress (62 people in intensive care; 3/30 [10%] with low-air-loss beds *v* 6/32 [19%] with alternating pressure mattresses; P = 0.35). [10] However, the RCT may have been underpowered to detect a clinically important difference between groups.

Harms: The reviews [7] [8] and the RCT [10] identified by the second review gave no information on adverse effects.

Comment: None.

OPTION MEDICAL SHEEPSKIN OVERLAYS TO PREVENT PRESSURE ULCERS

Incidence of pressure ulcers
Compared with standard care Medical sheep skin overlays alone or with standard pressure-area care may be more effective at reducing the incidence of pressure ulcers in people at risk of pressure ulcers (low-quality evidence).

For GRADE evaluation of interventions for pressure ulcers, see table, p 22 .

Benefits: We found two systematic reviews (search dates 2004 [7] and 2006 [8]). The second systematic review did not report outcomes data for included RCTs or perform a meta-analysis. [8] Instead, it gave a narrative summary of results. We have therefore reported results from the earlier review, [7] and have reported the further RCT identified by the second review separately. The first review identified one RCT (297 people), which found that medical sheepskin overlays significantly reduced pressure ulcers compared with standard care (proportion with pressure ulcers: 14/155 [9%] with medical sheepskin overlay *v* 43/142 [30%] with standard care; RR 0.30, 95% CI 0.17 to 0.52). [7] The second RCT (36 people) identified by the review was too small and poorly designed to detect a difference between groups; and the review reported no further data about the trial. [7] A third RCT (441 people aged at least 18 years admitted to hospital and deemed to be at low to moderate risk of pressure ulcers), [11] identified by the second systematic review, [8] also found that medical sheepskin overlays plus standard pressure-area care significantly reduced the incidence of pressure ulcers over an unspecified period compared with standard care (21/218 [10%] with medical sheepskin overlays plus standard pressure-area care *v* 37/223 [17%] with standard care alone; RR 0.58, 95% CI 0.35 to 0.96). However, these results should be interpreted with caution, as the analysis in this RCT was not by intention to treat; 539 people were randomised, and those who did not receive the allocated intervention (98/539 [18%]) were excluded from the analysis . [11] Standard care consisted of a standard hospital mattress with or without constant-low-pressure supports. [11]

Harms: The reviews gave no information on harms. [7] [8]

Comment: None.

OPTION ALTERNATING PRESSURE SURFACES TO PREVENT PRESSURE ULCERS

Incidence of pressure ulcers
Compared with standard foam mattress Alternating pressure surfaces may be more effective (very low-quality evidence).

Compared with constant-low-pressure supports We don't know whether alternating pressure surfaces are more effective than constant-low-pressure supports such as viscoelastic foam (very low-quality evidence).

Compared with each other We don't know whether one alternating pressure surface is more effective than the others (low-quality evidence).

For GRADE evaluation of interventions for pressure ulcers, see table, p 22 .

Benefits: We found two systematic reviews (search dates 2004, 11 RCTs [7] and 2006, 13 RCTs, 11 of which were included in the first review [8]) and one additional RCT [12] comparing alternating pressure surfaces versus standard foam mattresses, constant low pressure supports, or versus each other. The second systematic review [8] did not report outcomes data for included RCTs or perform a meta-analysis. Instead, it gave a narrative summary of results. We have therefore reported meta-analysis results from the earlier review, [7] and have reported further RCTs identified by the second review [8] separately.

Alternating pressure surfaces versus standard foam mattress:
One RCT (482 people) identified by the first review compared three interventions: alternating pressure (166 people), standard foam mattress (161 people), and water-filled mattress (155 people). [7] It found that an alternating pressure surface significantly reduced the incidence of pressure ulcers compared with a standard foam mattress (327 people: RR 0.32, 95% CI 0.14 to 0.74; NNT for 10 days' treatment 11, 95% CI 6 to 34). A second RCT (108 older hospitalised people confined to bed) [12] included in the second review [8] compared alternating pressure (both single- and double-layer air cell) mattresses versus a standard polyester foam mattress. [12] The RCT found that both alternating pressure mattresses significantly reduced pressure ulcers compared with standard foam mattresses (3% with double-layer air cell *v* 19% with single-layer air cell *v* 37% with standard foam; P less than 0.01 between all groups). However, this RCT did not undertake an intention-to-treat analysis, and only 68% of randomised participants were included in the analysis.

Alternating pressure surfaces versus constant-low-pressure supports:
The first review found no significant difference in the rates of pressure ulcer formation between alternating pressure and constant low pressure (8 RCTs, 1019 people, RR of developing a pressure ulcer 0.82, CI 0.57 to 1.19). [7] However, the meta-analysis pooled trials of several different types of surface and remains underpowered (the wide confidence intervals do not exclude a clinically important treatment effect). One RCT (447 people in hospital) identified by the second review [8] compared alternating pressure overlays versus a viscoelastic foam mattress plus standardised 4-hourly turning protocol for the prevention of pressure ulcers. [13] Study participants had grade 1 pressure ulcers or a Braden Scale score of less than 17. The RCT found no significant difference in the incidence of grade 2–4 pressure ulcers between treatment groups (AR of grade 2–4 pressure ulcer: 15.3% with alternating pressure *v* 15.6% with viscoelastic foam; P = 1.0); the duration of follow-up was unclear. The viscoelastic foam mattress group developed significantly more pressure ulcers on the heel (15% with alternating pressure *v* 46% with viscoelastic foam; P = 0.006). However, the alternating-pressure-overlay group developed more severe ulcers (77% grade 2 and 24% grade 3 or 4 ulcers with alternating pressure *v* 94% grade 2 and 6% grade 3 or 4 ulcers with viscoelastic foam mattress; P = 0.034). [13]

Alternating-pressure surfaces versus each other:
Three small RCTs (181 people) identified by the first review compared different alternating pressure devices versus each other; none found a significant difference (RR values all not significant), although all three RCTs were underpowered. [7] The second review [8] identified one large RCT (1972 acute and elective inpatients at least 55 years old admitted to vascular, orthopaedic, medical, or care-of-the-elderly wards) reported in two publications [14] [15] comparing alternating pressure mattresses versus alternating pressure mattress overlays. The RCT found no significant difference between groups in the proportion of people developing a new pressure ulcer of grade 2 or above (106/990 [10.7%] with overlay *v* 101/982 [10.3%] with mattress; mean difference 0.4%, 95% CI −2.3 to +3.1% P = 0.75). [15] A cost-effectiveness assessment of the trial found no significant difference between alternating pressure mattresses and overlays in mean time to development of an ulcer or hospital stay, although people using pressure mattresses took longer to develop an ulcer, and stayed in hospital for less time than people using overlays (development of an ulcer: mean difference 11 days, 95% CI –24 to +4 days; hospital stay: 19 days with mattress *v* 20 days with overlays, reported as non-significant, CI not reported, absolute numbers not reported for either outcome). [16]

Harms: The reviews, [7] [8] one RCT included in the second review, [13] and the additional RCT [12] gave no information on adverse effects. The RCT identified by the second review comparing alternating pressure mattresses versus alternating pressure overlays found a significantly higher proportion of people in the overlay group requested a mattress change because of dissatisfaction compared with people in the mattress group (230/990 [23%] with overlay *v* 186/982 [19%] with mattress; P = 0.02; mean difference 4.4%, 95% CI 0.7 to 7.9%). [15]

Comment: Most RCTs were small and of poor quality, and few performed the same comparison.

OPTION SEAT CUSHIONS TO PREVENT PRESSURE ULCERS

Incidence of pressure ulcers
Compared with each other Pressure-reducing cushions, foam seat cushions, and foam-and-gel seat cushions seem equally effective (moderate-quality evidence).

For GRADE evaluation of interventions for pressure ulcers, see table, p 22 .

Benefits: We found two systematic reviews (search dates 2004 [7] and 2006 [8]). The second systematic review [8] did not report outcomes data for included RCTs or perform a meta-analysis. Instead, it gave a narrative summary of results. We have therefore reported results from the earlier review, [7] and

have reported the further RCT identified by the second review separately. The first review identified three RCTs comparing different seat cushions. The first included RCT (52 people) compared slab-foam versus bespoke contoured foam cushions over 5 months' use; the second RCT (141 people) compared a gel-and-foam wheelchair cushion versus a foam cushion over 3 months; the third RCT (248 people) compared a slab-foam versus a contoured foam cushion over 3 months. None of the RCTs found a significant difference in the incidence of pressure ulcers between different types of cushions (first RCT: RR 1.06, CI 0.75 to 1.49; second RCT: RR 0.61, CI 0.37 to 1.00; third RCT: RR 1.00, 95% CI 0.84 to 1.18). [7] However, the confidence intervals of the RCTs suggest that they were probably underpowered to detect a clinically important difference between different cushions. The second review [8] identified a fourth small RCT (32 people aged at least 65 years and living in residential care) [17] comparing pressure-reducing seat cushions versus foam cushions (3-inch convoluted [eggcrate] foam) in people using wheelchairs. It found no significant difference between groups in the proportion of people with pressure ulcers at 1 year (10/17 [59%] with foam *v* 6/15 [40%] with pressure-reducing seat; P value not given; reported as not significant) or time until pressure ulceration (mean total days: 76.3 days with foam *v* 99.9 days with pressure reducing seat; reported as non-significant; P value not reported). [17]

Harms: The reviews [7] [8] and the RCT [17] in elderly wheelchair users identified by the second review gave no information on harms.

Comment: None.

OPTION ELECTRIC PROFILING BEDS TO PREVENT PRESSURE ULCERS

Incidence of pressure ulcers
Compared with standard hospital beds We don't know whether electric profiling beds are more effective at reducing the incidence of pressure ulcers at 10 days (low-quality evidence).

For GRADE evaluation of interventions for pressure ulcers, see table, p 22 .

Benefits: We found two systematic reviews (search dates 2004 [7] and 2006 [8]). The second systematic review [8] did not report outcomes data for included RCTs or perform a meta-analysis. Instead, it gave a narrative summary of results. We have therefore reported results from the earlier review. [7] . Both reviews identified the same RCT (70 people in medical or surgical hospital wards) comparing an electrically operated profiling bed (consisting of 4 sections plus a pressure-relieving foam mattress) versus a standard hospital bed with pressure-relieving mattress (foam or alternating-pressure). The RCT found no significant difference in the incidence of pressure ulcers up to 10 days (no one who received either intervention developed an ulcer). [7] The low event rate means that RCT was underpowered to detect a clinically important difference between groups.

Harms: The reviews gave no information about adverse effects. [7] [8]

Comment: None.

OPTION LOW-TECH CONSTANT LOW PRESSURE SUPPORTS TO PREVENT PRESSURE ULCERS

Incidence of pressure ulcers
Compared with other pressure-relieving devices We don't know whether low-tech constant low pressure supports are more effective at reducing the incidence of pressure ulcers (very low-quality evidence).

For GRADE evaluation of interventions for pressure ulcers, see table, p 22 .

Benefits: We found two systematic reviews (search dates 2004 [7] and 2006 [8]). Both reviews identified the same seven RCTs (1451 people; trial size 36–100 people) about the effects of low-tech constant low pressure supports in preventing pressure ulcers, which were underpowered (because few people in the trial developed pressure ulcers and the probability of small differences between surfaces that work in similar ways), or too flawed to produce reliable conclusions. [7] The first review [7] did not perform a meta-analysis because of heterogeneity among the trials in types of support and comparisons assessed, and the second review was narrative in character. [8]

Harms: The reviews gave no information about adverse effects. [7] [8]

Comment: Most RCTs were small and of poor quality, and few performed the same comparison.

OPTION NUTRITIONAL SUPPLEMENTS TO PREVENT PRESSURE ULCERS

Incidence of pressure ulcers
Compared with control or standard care We don't know whether nutritional supplements are more effective at reducing the incidence of pressure ulcers (very low-quality evidence).

For GRADE evaluation of interventions for pressure ulcers, see table, p 22 .

Benefits: We found two systematic reviews (search dates 2004 [18] and 2006 [8]) assessing parenteral and enteral nutritional supplements. The second systematic review [8] did not report outcomes data for included RCTs or perform a meta-analysis. Instead, it gave a narrative summary of results. We have therefore reported results from the earlier review, [7] and have reported the further RCT identified by the second review separately.The first review [18] identified four RCTs (974 people) comparing a combination of nutritional supplements consisting of a minimum of energy and protein in different dosages. The largest RCT found that oral nutritional supplementation reduced pressure ulcers at 15 days compared with control, and that the reduction just reached significance (672 acutely ill people aged over 5 years; AR of pressure ulcers: 118/295 [40%] with supplementation *v* 181/377 [48%] with control; RR 0.83, 95% CI 0.70 to 0.99). However, treatment groups were not comparable at baseline. [18] The other three smaller RCTs all found a trend toward reduced pressure ulcers with supplements compared with control, but were too small to detect a clinically important difference (first RCT, 59 people: RR at 6 months 0.22, 95% CI 0.01 to 4.28; second RCT, 140 people: RR at 2 weeks 0.92, 95% CI 0.64 to 1.32; third RCT, 103 people: RR at 28 days 0.92, 95% CI 0.65 to 1.30). The second review [8] identified a further RCT (501 people newly admitted to long-term care; mean age 80.1 years) comparing an oral nutritional supplement (200 ml containing 8 g protein, 8 g fat, 23.6 g carbohydrates, 838 kJ, vitamins, and minerals given twice daily) versus standard care (standard hospital diet of 2200 kcal/day). [19] A slightly lower proportion of people taking nutritional supplements developed pressure sores at 182 days (10% with supplement group *v* 12% with control; significance not reported). [19]

Harms: The reviews gave no information on adverse effects. [18] [8]

Comment: Most of the RCTs in the reviews had weak methods. [18] [8] Flaws included lack of information about the method of randomisation, lack of blinding of outcome assessment, high withdrawal rates, and lack of intention-to-treat analyses.

OPTION REPOSITIONING (INCLUDING REGULAR "TURNING") TO PREVENT PRESSURE ULCERS

Incidence of pressure ulcers
Repositioning compared with standard care Four-hourly repositioning in combination with a viscoelastic foam mattress may be more effective than standard care or other turning regimens (low-quality evidence).

Repositioning at 30 degree tilt versus a 90 degree lateral and supine position We don't know whether repositioning including regular turning or a 30 degree tilt position is more effective (low-quality evidence).

For GRADE evaluation of interventions for pressure ulcers, see table, p 22 .

Benefits: We found two systematic reviews (search dates 1995 [20] and 2006). The second systematic review [8] did not report outcomes data for included RCTs or perform a meta-analysis, but instead gave a narrative summary of results. We have therefore reported results from the earlier review, [20] and have reported further RCTs identified by the second review [8] separately.

Repositioning versus control, usually standard care:
The first review (3 RCTs, 217 people; see comment below) reported that none of the RCTs it identified found a significant difference in the incidence of pressure ulcers between regular manual repositioning and control treatment (reported as not significant, no statistical data reported). [20] Control was standard care in two RCTs. The third RCT compared four interventions: repositioning, small-cell ripple bed, foam mattress, and standard care. The review reported that the RCTs were all too small and weak to detect clinically important differences between treatments. The first RCT (838 people) identified by the second review [8] compared five groups over a 4-week period in people with Braden scores less than 17 (see comment). [21] The groups received: turning every 2 hours on a standard mattress (65 people); turning every 3 hours on a standard mattress (65 people); turning every 4 hours on a viscoelastic foam mattress (67 people); turning every 6 hours on a viscoelastic foam mattress (65 people); or standard care (576 people). Standard care involved preventive measures, including water mattresses, alternating mattresses, sheepskins, and gel cushions, given at the nurses' discretion. The combination of turning every 4 hours and placement on a viscoelastic foam mattress significantly reduced pressure-ulcer development compared with standard

care and the other turning regimens (838 people randomised, 761 analysed; AR of pressure ulcers: 14% with 2-hour turning *v* 24% with 3-hour turning *v* 3% with 4-hour turning plus viscoelastic mattress *v* 16% with 6-hour turning plus viscoelastic mattress *v* 20% with standard care; 4-hour turning *v* standard care: OR 0.12, 95% CI 0.03 to 0.48; difference between 4-hour turning and other regimens reported as significant, P value not reported). There was no significant difference between the other turning regimens and standard care (P greater than 0.05 for all other turning regimens *v* standard care). The development of pressure ulcers was also significantly delayed in the group receiving 4-hourly changes of position on a viscoelastic foam mattress (results displayed graphically; P = 0.001). [21]

Repositioning at 30 degree tilt versus a 90 degree lateral and supine position:
The second review [8] identified one RCT (46 hospitalised elderly people) [22] that compared putting people in a 30 ° tilt position (pillows placed under one buttock and under each leg so that pelvis was tilted at 30 ° and the sacrum and heels were not in contact with support surface) versus a 90 ° lateral and supine position. [22]] It found no significant difference between groups in the proportion of people who developed pressure ulcers at 24 hours (non-blanching erythema: 3/23 [13%] in 30 ° group *v* 2/23 [9%] in 90 ° group; P greater than 0.05; visible breaks in the epidermis: 0/23 [0%] in 30 ° group *v* 0/23 [0%] in 90 ° group; reported as non-significant, P value and significance not reported). The RCT found that a significantly higher proportion of people in the 30 ° tilt group found the position difficult to maintain compared with people in the 90 ° tilt group (20/23 [87%] in 30 °group *v* 5/23 [22%] in 90 ° group; P less than 0.05). [22]

Harms: The reviews [20] [8] and the two RCTs [21] [22] identified by the second review gave no information about harms.

Comment: The three RCTs identified by the first review were small, of poor quality, and no comparisons were undertaken more than once. [20] In one of the RCTs of regular repositioning identified by the review, 23 people were randomised to repositioning, but only 10 people actually were repositioned regularly. [20] The subsequent RCT cluster randomised hospital wards to each turning regimen. [21] Within each ward, five people were randomly selected for the intervention, and the remainder allocated to standard care.

OPTION TOPICAL LOTIONS AND DRESSINGS TO PREVENT PRESSURE ULCERS

Incidence of pressure ulcers
Compared with placebo/other lotions We don't know whether topical lotions are more effective at preventing pressure ulcers (very low-quality evidence).

Note
We found no direct information about dressings for the prevention of pressure ulcers ulcers.

For GRADE evaluation of interventions for pressure ulcers, see table, p 22 .

Benefits: We found two systematic reviews (search dates 2000, 2 RCTs [23] and 2006, 3 RCTs [8]). The second systematic review [8] did not report outcomes data for included RCTs or perform a meta-analysis. Instead, it gave a narrative summary of results. We have therefore reported results from the earlier review, [23] and have reported further RCTs identified by the second review individually.The first RCT (319 people) identified by the first review compared hexachlorophene (hexachlorophane) lotion versus cetrimide lotion, found no significant difference in the incidence of new pressure ulcers over 3 weeks (OR 0.87, 95% CI 0.46 to 1.65; no absolute data reported). [23] These results must be interpreted with caution, as they were based on a completer analysis of 167 people. The second RCT (120 people) identified by the review compared hexachlorophene lotion versus an inert lotion, and found no significant difference in the proportion of people with changes in skin condition over 3 weeks. [23] A third RCT [23] identified by the second systematic review [8] compared twice-daily topical application of a compound of eight hyperoxygenated fatty acids to pressure areas versus application of a placebo compound of identical appearance and fragrance, in people at medium to very high risk of pressure ulcers. A completer analysis concluded that significantly fewer pressure ulcers developed with topical fatty acids than with topical placebo (380 people randomised; AR of pressure ulcer: 12/164 [7%] with fatty acids *v* 29/167 [17%] with placebo; RR 0.42, 95% CI 0.22 to 0.80). In the absence of an intention-to-treat analysis, this result must be viewed with caution (13% of those randomised were not included in the analysis). [24] The reviews identified no RCTs assessing dressings for pressure-ulcer prevention. [23] [8]

Harms: The reviews [23] [8] and the RCT [24] identified by the second review gave no information about adverse effects.

Comment: None.

OPTION AIR-FILLED VINYL BOOTS TO PREVENT PRESSURE ULCERS

Incidence of pressure ulcers
Compared with hospital pillows Air-filled vinyl boots with foot cradles are less effective at reducing the rate of pressure-ulcer development (moderate-quality evidence).

For GRADE evaluation of interventions for pressure ulcers, see table, p 22 .

Benefits: We found two systematic reviews (search dates 2004 [7] and 2006 [8]). The second systematic review [8] did not report outcomes data for included RCTs or perform a meta-analysis, but instead gave a narrative summary of results. We have therefore reported results from the earlier review. [7] . Both reviews identified one small RCT (52 people), which found that a vinyl boot (air-filled with a built in foot cradle) was significantly less effective than hospital pillows in reducing the rate of developing pressure ulcers (mean time to skin breakdown: 10 days with vinyl boot *v* 13 days with pillow; P less than 0.036 log rank test). [7] [8]

Harms: The reviews gave no information about harms. [7] [8]

Comment: None.

OPTION HYDROCELLULAR HEEL SUPPORTS TO PREVENT PRESSURE ULCERS

Incidence of pressure ulcers
Compared with orthopaedic wool padding Hydrocellular heel supports may be more effective at 8 weeks at reducing the incidence of pressure ulcers (low-quality evidence).

For GRADE evaluation of interventions for pressure ulcers, see table, p 22 .

Benefits: We found one systematic review [8] (search date 2006), which identified one RCT comparing the use of hydrocellular heel supports versus orthopaedic wool padding to prevent heel pressure ulcers. [25] A completer analysis found that the hydrocellular heel supports significantly reduced the incidence of pressure ulcers over 8 weeks compared with orthopaedic wool padding (130 people; 2/61 [3%] with hydrocellular supports *v* 22/50 [44%] with wool padding; RR 0.07, 95% CI 0.02 to 0.30). [25] These results should be interpreted with caution because of the lack of intention-to-treat analysis.

Harms: The review [8] and the RCT gave no information on adverse effects. [25]

Comment: None.

OPTION LOW-AIR-LOSS HYDROTHERAPY BEDS TO PREVENT PRESSURE ULCERS

Incidence of pressure ulcers
Compared with support surfaces Low-air-loss hydrotherapy beds are less effective at 60 days at reducing the risk of developing pressure ulcers in people who are incontinent (moderate-quality evidence).

For GRADE evaluation of interventions for pressure ulcers, see table, p 22 .

Benefits: We found two systematic reviews (search dates 2004 [7] and 2006 [8]). The second systematic review [8] did not report outcomes data for included RCTs or perform a meta-analysis. Instead, it gave a narrative summary of results. We have therefore reported results from the earlier review. [7] Both reviews identified one RCT (98 people with incontinence, admitted to acute and long-stay hospital wards). It found that low-air-loss hydrotherapy beds increased the risk of developing a pressure ulcer compared with a range of support surfaces after 60 days; this increase did not reach statistical significance (8/42 [19%] with low-air-loss hydrotherapy beds *v* 4/56 [7%] with support surfaces; RR 2.67, 95% CI 0.86 to 8.37). [7] [8] The RCT is likely to have been underpowered to detect a clinically important difference between groups.

Harms: The reviews gave no information on adverse effects. [7] [8]

Comment: None.

QUESTION What are the effects of treatments in people with pressure ulcers?

OPTION AIR-FLUIDISED SUPPORT TO TREAT PRESSURE ULCERS

Healing rates
Compared with standard care Air-fluidised supports may be more effective at 15 days at increasing healing rates of established pressure ulcers (very low-quality evidence).

For GRADE evaluation of interventions for pressure ulcers, see table, p 22 .

Benefits: We found one systematic review (search date 2000, 3 RCTs, 202 people) comparing air-fluidised supports versus standard care. [26] Two RCTs (105 people in hospital) found that significantly more established pressure ulcers were healed in people using air-fluidised supports than in people having standard care (alternating pressure mattresses, regular changes of position, sheepskin, gel pads, or limb protectors) after a mean 15 days (first RCT: median change in total ulcer surface area: –1.2 cm^2 with air-fluidised support *v* +0.5 cm^2 with standard care; second RCT: mean size of ulcers reduced with air-fluidised support *v* increased with standard care; P = 0.05, absolute numbers not reported). The third RCT (97 people being cared for at home) found no significant difference after 36 weeks (reported as not significant; no further data reported), although this RCT had a 13% withdrawal rate and did not perform an intention-to-treat analysis.

Harms: The review gave no information on adverse effects. [26]

Comment: People are unable to move in and out of bed independently when they use air-fluidised beds, and this limits the number of people for whom they are suitable.

OPTION ALTERNATING PRESSURE SURFACES TO TREAT PRESSURE ULCERS

Healing rates
Compared with each other/standard care Alternating-pressure mattresses, fluid-filled mattress overlays, and standard care seem equally effective at increasing healing rates (moderate-quality evidence).

For GRADE evaluation of interventions for pressure ulcers, see table, p 22 .

Benefits: We found one systematic review (search date 2000, 3 RCTs), [26] and one subsequent RCT. [27] Two RCTs identified by the review (182 older people with pressure ulcers in hospital) found no significant difference in rates of healing of pressure ulcers with different alternating-pressure mattresses after 4 and 18 weeks (reported as not significant, CI not reported). [26] The third RCT in the review (32 older people in hospital and nursing homes) found no significant difference in healing of pressure ulcers after 2 weeks between an alternating pressure mattress and standard care (reported as not significant, CI not reported). The subsequent RCT (158 people with pressure ulcers) found no significant difference in progress of pressure ulcers between an alternating pressure mattress replacement and a static, fluid-filled mattress overlay (overall ulcer and worst-ulcer progress classified as worse, no change, or improved: overall ulcer progress, P = 0.67; worst-ulcer progress, P = 0.053). [27]

Harms: The review gave no information on adverse effects. [26]

Comment: People often have difficulty moving in bed independently on alternating-pressure mattresses. [14]

OPTION DEBRIDEMENT TO TREAT PRESSURE ULCERS

Healing rates
Debriding agents compared with each other We don't know whether one debriding agent is more effective than the others at increasing healing rates of pressure ulcers (very low-quality evidence).

Note
We found no clinically important results about debridement compared with no debridement in the treatment of people with pressure ulcers.

For GRADE evaluation of interventions for pressure ulcers, see table, p 22 .

Benefits: We found one systematic review (search date 1998) [28] and five subsequent RCTs. [29] [30] [31] [32] [33] The systematic review found no RCTs comparing debridement versus no debridement. [28] It identified 32 RCTs comparing different debriding agents such as dextranomer paste, but the studies were small, included a range of wounds, and few comparisons were undertaken in more

than one RCT. The review concluded that there was insufficient evidence to promote the use of any particular debriding agent over another. The subsequent RCTs compared a variety of agents versus each other or versus dressings. [29] [30] [31] [32] [33] All but one were small, and together they provided no conclusive evidence about the relative effectiveness of the agents (see table 1, p 21).

Harms: The review [28] and subsequent RCTs [29] [30] [31] [32] [33] provided no good evidence on adverse effects.

Comment: None.

OPTION HYDROCOLLOID DRESSINGS TO TREAT PRESSURE ULCERS

Healing rates

Compared with gauze soaked in saline, hypochlorite, or povidone iodine We don't know whether hydrocolloid dressings are more effective at improving healing rates of ulcers (very low-quality evidence).

Compared with other dressings Hydrocolloid dressings and alginate dressings seem equally effective at 8 weeks at increasing ulcer-healing rates (moderate-quality evidence).

Compared with topical phenytoin We don't know whether hydrocolloid dressings are more effective at increasing ulcer-healing rates (very low-quality evidence).

For GRADE evaluation of interventions for pressure ulcers, see table, p 22 .

Benefits:

Hydrocolloid dressings versus standard dressings (gauze soaked in saline, hypochlorite, or povidone iodine):

We found two systematic reviews (search date 1997, 5 RCTs; 396 wounds; search date 2003, 6 RCTs including 4 RCTs identified by the earlier review; 286 people) [34] [35] and one subsequent RCT [36] of dressings or topical agents for pressure ulcers. The first review found that hydrocolloid dressings significantly improved healing up to 75 days compared with standard dressings (wounds healed: 102/205 [50%] with hydrocolloid dressing *v* 59/191 [31%] with standard dressing; OR 2.57, 95% CI 1.58 to 4.18). [34] Standard dressings included gauze soaked in saline, hypochlorite, or povidone iodine. The second review [35] included two additional RCTs. The first additonal RCT found that hydrocolloid dressings significantly improved healing compared with gauze soaked in saline (32 people; relative volume of wound at 12 weeks relative to 100% at baseline: 26% with hydrogel *v* 64% with saline; P less than 0.02). [37] The second additional RCT found no significant difference in the proportion of people with complete ulcer healing between hydrocolloid dressings and gauze soaked in povidone iodine (44 people; AR for ulcer healing: 21/26 [81%] with hydrocolloid *v* 14/18 [78%] with povidone iodine gauze; difference reported as not significant, P value not reported). [38] The subsequent RCT compared three treatments: hydrocolloid dressing, standard dressing (gauze soaked in saline), and topical phenytoin. [36] It found that hydrocolloid dressing significantly increased the proportion of people with complete ulcer healing at 8 weeks compared with standard dressings (3-arm RCT, 83 people, duration of follow-up not reported; AR for complete healing: 20/28 [71%] with hydrocolloid dressing *v* 8/27 [30%] with standard dressing; ARI 41.8%, 95% CI 17.7% to 65.8%; P less than 0.005). However, in this RCT there were important between-group differences at baseline for ulcer size (mean size: 7 cm^2 with hydrocolloid dressing *v* 5 cm^2 with topical phenytoin *v* 10 cm^2 with standard dressing; P greater than 0.10). [36] Although these differences were not statistically significant, they may have biased the results against standard dressings. Overall, RCTs were small and of poor quality, and the significance of the meta-analysis in the first review was sensitive to the method of calculation (see comment below).

Hydrocolloid dressings versus other dressings:

We found two systematic reviews (search date 1997, 9 RCTs, 713 people; [34] search date 2003, 8 RCTs, including 4 RCTs included in the first review, 481 people) [35] and one subsequent small RCT (83 people) compared hydrocolloid versus other dressings. [39] Neither review found a significant difference between hydrocolloid and other dressings in meta-analyses. [34] [35] However, the RCTs included in the reviews had weak methods and were too small to draw reliable conclusions. The first subsequent RCT compared hydrocolloid dressings for 8 weeks versus a combination of alginate dressings for 4 weeks followed by hydrocolloid dressings for 4 weeks. [39] There was no significant difference between the two groups in the proportion of people whose ulcers had healed at 8 weeks (110 people; AR for ulcer healing: 8/53 [15%] with hydrocolloid alone *v* 3/57 [5%] with alginate followed by hydrocolloid; P = 0.162). [39]

Hydrocolloid dressings versus topical phenytoin:

See benefits of topical phenytoin, p 17 .

Harms:

Hydrocolloid dressings versus gauze soaked in saline, hypochlorite, or povidone iodine:
The first review gave no information on adverse effects. [34] The second review reported isolated occurrences of procedural pain and hypergranulation with hydrocolloid dressings. Meta-analysis in this review found no significant difference in withdrawals due to adverse effects between those receiving advanced dressings (mainly hydrocolloid) and those treated with standard dressings (5 RCTs, 4 of hydrocolloids, 188 people; RR 0.89, 95% CI 0.36 to 2.18). [35] The subsequent RCT reported that there were 'no major adverse events'. [36]

Hydrocolloid dressings versus other dressings:
The first review gave no information on adverse effects. [34] The second review reported that adverse effects included maceration, dressing intolerance, sticking of dressing leading to bleeding, and infection (groups affected and absolute numbers not reported). [35] In the subsequent RCT more pain was reported during dressing removal in the group receiving hydrocolloid dressings compared with those receiving the combination of alginate followed by hydrocolloids (AR for pain on removal: 36% with hydrocolloid alone *v* 31% with alginate followed by hydrocolloid; P = 0.03). [39]

Hydrocolloid dressings versus topical phenytoin:
See harms of topical phenytoin, p 17 .

Comment:

Hydrocolloid dressings versus gauze soaked in saline, hypochlorite, or povidone iodine:
Given the large absolute risks of events in the first review, [34] a relative risk would be a preferable outcome measure for results. [40] If the meta-analysis is re-worked using relative risk instead of odds ratio, the result is no longer significant (Cullum N, 2004; personal communication).

OPTION DRESSINGS OTHER THAN HYDROCOLLOID TO TREAT PRESSURE ULCERS

Healing rates
When assessing dressings other than hydrocolloid, we don't know whether one type of dressing is more effective than others at improving healing rates of pressure ulcers (very low-quality evidence).

For GRADE evaluation of interventions for pressure ulcers, see table, p 22 .

Benefits:

We found two systematic reviews (search date 1997, 7 RCTs, 463 people; [34] search date 2003, 7 RCTs, including 4 identified by the earlier review, 238 people), [35] two additional, and five subsequent RCTs assessing dressings other than hydrocolloids. Overall, the RCTs had weak methods and were too small to draw reliable conclusions. [41] [42] [43] [44] [45] [46] [47] The first subsequent RCT found no significant difference in wound healing between protease modulating matrix and standard gauze dressing with povidone iodine disinfection (80 people; AR for wound healing: 36/40 [90%] with protease modulating matrix *v* 28/40 [70%] with standard dressing; P = 0.59). [45] The second subsequent RCT found that hydrogel increased healing compared with povidone iodine gauze (27 people, 49 ulcers, ulcers were the unit of randomisation; AR for healing: 84% with hydrogel *v* 54% with povidone iodine gauze; P = 0.04). [48] The third subsequent RCT (99 people, 71/99 [71%] with venous leg ulcers, 28/99 [28%] with infected grade III and IV pressure ulcers), reported in two publications [47] [46] compared silver-releasing hydroalginate dressing versus pure calcium alginate dressing. Pre-planned subgroup analysis in people with pressure ulcers found that silver hydroalginate was associated with greater improvement at 4 weeks than pure calcium alginate in wound area and wound severity scores (28 people, change in median wound area [baseline range: 22.4 to 22.5 cm^2]: −7.2 cm^2 with silver dressing *v* −0.8 cm^2 with calcium alginate dressing; change in median wound severity score [baseline range: 17.4 to 17.6]: −5.5 with silver dressing *v* −3.6 with calcium alginate dressing; P values not reported for either outcome). [47] [46]

Harms:

The first review gave no information on adverse effects. [34] The second review identified isolated reports of procedural pain associated with dextranomer dressings, and minor skin reactions with a range of dressings. [35] Four of the additional and subsequent RCTs reported no adverse effects associated with dressings, but were likely to have been underpowered to detect clinically important adverse effects. [41] [42] [43] [45] One subsequent RCT did not give information on adverse events. [48] Another subsequent RCT found that one person using silicone dressings developed hypergranulation tissue, and three people using hydropolymer dressings had adverse effects, including development of hypergranulation tissue, new wounds, redness, and irritation. [44] In the RCT comparing silver-releasing hydroalginate dressing versus pure calcium alginate dressing, one person in the silver-releasing hydroalginate dressing group reported poor local acceptability and/or tolerability. [47] [46] See also harms of hydrocolloid dressings versus other dressings, p 12 .

Comment:

None.

OPTION ELECTROTHERAPY TO TREAT PRESSURE ULCERS

Healing rates
Compared with sham electrotherapy We don't know whether electrotherapy is more effective at 3–12 weeks at increasing healing rates of pressure ulcers (very low-quality evidence).

For GRADE evaluation of interventions for pressure ulcers, see table, p 22 .

Benefits:

Electrotherapy versus sham electrotherapy:
We found one systematic review (search date 2000, 3 RCTs), [26] and one subsequent RCT. [49] Two of the RCTs (91 pressure ulcers) included in the review were suitable for inclusion in a meta-analysis, which found that electrotherapy significantly increased healing after about 3–5 weeks compared with sham treatment (RR 7.92, 95% CI 2.40 to 26.30). The third RCT (49 people) included in the review found similar results after 4 weeks (% area of pressure ulcer healed: 50% with electrotherapy *v* 23% with sham; P = 0.042). [50] These RCTs were small, however, and had important weaknesses in their methods. Results should therefore be interpreted with caution. The subsequent double-blind RCT compared the use of electrotherapy versus sham therapy for 8 weeks, and followed up for a further 12 weeks. [49] There were no significant differences between the groups in the proportion of participants completely healed at the end of 8 weeks' treatment (63 people; AR for healing: 5/35 [14%] with electrotherapy *v* 3/28 [11%] with sham therapy; P = 0.39), or at 12 weeks' follow-up (AR for healing: 9/35 [26%] with electrotherapy *v* 10/28 [36%] with sham therapy; P = 0.28). It found no significant difference in the time to complete healing (mean time: 63 days with electrotherapy *v* 90 days with sham therapy; P = 0.16). [49]

Harms:

Electrotherapy versus sham electrotherapy:
The review gave no information on adverse effects. [26] The subsequent RCT reported that two people in the electrotherapy group had hypergranulation of the ulcer, and two had local irritation (2/35 [6%] for either outcome), possibly as a result of concomitant use of topical sulfadiazine cream. [49] No further potentially treatment-related adverse events were reported.

Comment:

None.

OPTION LOW-AIR-LOSS BEDS TO TREAT PRESSURE ULCERS

Healing rates
Compared with convoluted foam We don't know whether low-air-loss beds are more effective at increasing pressure-ulcer healing rates (low-quality evidence).

For GRADE evaluation of interventions for pressure ulcers, see table, p 22 .

Benefits:

We found one systematic review (search date 2000), which found no significant difference in pressure-ulcer healing between low-air-loss beds and convoluted foam (2 RCTs, 133 people: RR 1.25, 95% CI 0.84 to 1.86). [26] The meta-analysis may have been underpowered to detect a clinically important difference between groups. We found no RCTs that compared low-air-loss beds versus alternating pressure or air-fluidised supports.

Harms:

The systematic review [26] noted that, in one of the RCTs identified, hypothermia was found in a small number of people who used low-air-loss hydrotherapy beds. [51]

Comment:

None.

OPTION LOW-LEVEL LASER TREATMENT TO TREAT PRESSURE ULCERS

Healing rates
Compared with standard care/sham treatment We don't know whether laser treatment is more effective at increasing pressure-ulcer healing rates (low-quality evidence).

Compared with ultrasound plus ultraviolet light Laser treatment and ultrasound plus ultraviolet light seem equally effective at increasing the number of sores healed at 12 weeks (moderate-quality evidence).

For GRADE evaluation of interventions for pressure ulcers, see table, p 22 .

Benefits:

Low level laser treatment versus standard care or sham treatment:
We found three systematic reviews (search dates 1998, 1 RCT, 18 people; [52] search date 2004, 3 RCTs, 180 people; [53] search date 2004, 3 RCTs, 120 people; [54]) comparing low-level laser therapy versus standard care or sham laser in people with pressure ulcers. We also found one

subsequent RCT (35 people). [55] The reviews together identified four RCTs (200 people with stage 2 or 3 pressure ulcers) of small sample size, three of which were poor quality. The first RCT (high quality, 86 people) identified by the reviews found similar rates of complete wound-healing at 6 weeks (18/36 [50%] with laser treatment *v* 15/43 [35%] with standard care; P value not reported). [53] The second RCT (poor quality, 74 people) identified by the reviews found that people having laser treatment had significantly greater reduction in ulcer area at 4 weeks compared with people having standard care (79% decrease with laser treatment *v* 57% decrease with standard care; P less than 0.05). These results should be treated with caution, as the analysis was not by intention to treat, and 15/74 [20%] people withdrew from the trial. The trial also only reported outcomes at 4 weeks despite having a 10-week treatment period. The other two RCTs (40 people) identified by the reviews were too small or flawed to draw conclusions. The subsequent RCT was also flawed, as it analysed multiple pressure ulcers on individual people as though they were independent. However, it found no significant difference in pressure-ulcer healing between laser and sham laser (P = 0.802). [55]

Low level laser treatment versus ultrasound plus ultraviolet light:
See benefits of therapeutic ultrasound, p 17 .

Harms: The RCTs identified by the reviews gave no information on adverse effects. [52] [53] [54]

Low level aser treatment versus ultrasound plus ultraviolet light:
See harms of therapeutic ultrasound, p 17 .

Comment: Both recent reviews conclude that there is currently no evidence that low-level laser speeds wound healing. [53] [54]

OPTION LOW-TECH CONSTANT-LOW-PRESSURE SUPPORTS TO TREAT PRESSURE ULCERS

Healing rates
Compared with each other We don't know whether a layered-foam replacement mattress is more effective than a water mattress at 4 weeks at increasing healing rates of pressure ulcers (low-quality evidence).

For GRADE evaluation of interventions for pressure ulcers, see table, p 22 .

Benefits: We found one systematic review (search date 2000), which identified one RCT (120 elderly people with pressure ulcers in a nursing home) that found similar rates of pressure-ulcer healing after 4 weeks between a layered-foam replacement mattress and a water mattress (45% with layered foam *v* 48% with water; CI not reported). [26]

Harms: The review gave no information on adverse effects. [26]

Comment: None.

OPTION NUTRITIONAL SUPPLEMENTS TO TREAT PRESSURE ULCERS

Healing rates
Compared with control (low dose or no supplements) We don't know whether nutritional supplements are more effective at 3 weeks to 84 days at increasing healing rates of pressure ulcers (very low-quality evidence).

For GRADE evaluation of interventions for pressure ulcers, see table, p 22 .

Benefits: We found one systematic review (search date 2002, 4 RCTs, 134 people with existing pressure ulcers), [18] and two subsequent RCTs. [56] [57] The review did not pool data. The first included RCT (88 people with pressure ulcers in nursing homes or hospital, some of whom were receiving ultrasound treatment for their pressure ulcers) found no significant difference in ulcer healing at 84 days between ascorbic acid 1000 mg daily and ascorbic acid 20 mg daily (healing: 17/43 [39%] with ascorbic acid 1000 mg/day *v* 22/45 [49%] with ascorbic acid 20 mg/day; RR 0.81, 95% CI 0.50 to 1.30). The second included RCT (20 people with pressure ulcers having surgery) identified by the review found no significant difference in ulcer healing at 4 weeks between ascorbic acid (1000 mg/day for 4 weeks) and placebo (RR of ulcer healing 2.00, 95% CI 0.68 to 5.85). The third included RCT (12 institutionalised people being fed through a tube) identified by the review found no significant difference in ulcer healing at 8 weeks between a very high-protein diet and a high-protein diet (RR of healing 0.11, 95% CI 0.01 to 1.70). The fourth included RCT (14 people) identified by the review was a crossover RCT that did not report results before the crossover period, and had a high withdrawal rate. The first subsequent RCT compared three different diets for 3 weeks in people with stage 2 or 3 pressure ulcers. [56] The diets were a standard hospital diet (diet A); a standard hospital diet plus a daily supplement of 500 kcal, protein 18 g, vitamin C 72 mg, and zinc

7.5 g (diet B); and a standard hospital diet plus 500 kcal, protein 21 g, vitamin C 500 mg, zinc 30 mg, and arginine 9 g (diet C). The RCT found that diet C significantly improved ulcer healing, as measured by a reduction in Pressure Ulcer Scale for Healing (PUSH) score, at 3 weeks compared with diet A or diet B (16 people in hospital; PUSH score range 0 [completely healed] to 17 [greatest severity]; mean PUSH score: 7.0 with diet A *v* 6.0 with diet B *v* 2.6 with diet C; P less than 0.05 for comparison of diet C *v* diets A or B). However, this study randomised only 16 people between the three groups and did not report the proportion of participants with complete healing. The second subsequent RCT (89 people resident in long-term care facilities with stage II, III, or IV pressure ulcers) compared a concentrated, fortified, collagen protein hydrolysate supplement versus placebo, administered orally or via feeding tubes. [57] The RCT found that people taking supplements had significantly better PUSH scores at 8 weeks than people taking placebo (PUSH scores: 3.55 with supplement *v* 3.22 with placebo; P less than 0.05). However, these results should be interpreted with caution, as groups were imbalanced at baseline (mean PUSH scores at baseline: 9.11 in people receiving supplements *v* 6.07 in people taking placebo) and results were not based on intention-to-treat analysis.

Harms: Neither the review [18] nor the first subsequent RCT [56] gave information on adverse effects. The second subsequent RCT reported that there was no significant difference between groups in adverse effects (P greater than 0.05). [57] It reported that 11/44 [25%] people discontinued treatment because of adverse effects (2 with hip fracture because of fall; 3 because of changes in renal lab values; 4 with nausea or distension; 2 died) but did not report data for each group separately, except to say that one person in each group died from causes unrelated to treatment.

Comment: Three of the RCTs identified by the review [18] and the subsequent RCTs [56] [57] were small and may have lacked power to detect clinically important differences between treatments. The second subsequent RCT used alternate randomisation design. [57]

OPTION SEAT CUSHIONS TO TREAT PRESSURE ULCERS

Healing rates
Compared with each other We don't know whether one type of seat cushion is more effective than others at increasing pressure-ulcer healing rates (low-quality evidence).

For GRADE evaluation of interventions for pressure ulcers, see table, p 22 .

Benefits: We found one systematic review (search date 2000, 1 RCT, 25 people), [26] and one subsequent RCT (207 people). [58] The RCT identified by the review compared two different seat cushions (cushion with dry flotation versus alternating-pressure cushion) and found no significant difference between different cushions in the number of ulcers completely healed (reported as not significant, no further data reported). [26] The subsequent RCT (207 people with grade 3 and 4 pressure ulcers) compared three interventions over 6 months: a bespoke, moulded seat containing alternating-pressure air sacs; a solid-foam bed overlay 8.9 cm thick; and a low-air-loss bed. The RCT had several flaws, including a lack of intention-to-treat analysis (participants who worsened were excluded from analysis), and a primary outcome that was determined by the results of the trial. It found that the seat cushion significantly increased time to healing compared with either other surface (median time to healing: 3.33 months with cushion *v* 4.38 months with low-air-loss bed *v* 4.55 months with foam overlay; P less than 0.001 for seat cushion *v* either comparator). [58]

Harms: The review [26] and subsequent RCT [58] gave no information on adverse effects.

Comment: None.

OPTION SURGERY TO TREAT PRESSURE ULCERS

We found no direct information about surgery in the treatment of pressure ulcers.

For GRADE evaluation of interventions for pressure ulcers, see table, p 22 .

Benefits: We found no systematic review or RCTs of surgical treatments for pressure ulcers.

Harms: We found no RCTs.

Comment: None.

OPTION THERAPEUTIC ULTRASOUND TO TREAT PRESSURE ULCERS

Healing rates
Compared with control Therapeutic ultrasound may be no more effective than sham ultrasound at increasing pressure-ulcer healing rates (low-quality evidence).

Ultrasound plus ultraviolet compared with standard care or laser treatment Ultrasound plus ultraviolet is no more effective at increasing the number of sores healed at 12 weeks (moderate-quality evidence).

For GRADE evaluation of interventions for pressure ulcers, see table, p 22 .

Benefits:

Ultrasound versus sham ultrasound:
We found one systematic review (search date 2006, 3 RCTs). [59] The review found no significant difference between therapeutic ultrasound and sham ultrasound (2 RCTs, 128 people: RR 0.97, 95% CI 0.65 to 1.45). One RCT assessed outcomes at 12 weeks; the other RCT did not report the timing of outcome assessment.

Ultrasound plus ultraviolet light versus standard care or versus laser treament:
One RCT (20 people) included in the review compared three interventions: ultrasound plus ultraviolet (UV) light; laser treatment; and standard care. [59] It found no significant difference in the number of sores healed at 12 weeks between ultrasound plus UV and standard care (6/6 [100%] with ultrasound plus UV *v* 5/6 [83%] with standard care; P = 0.3; RR 1.20, 95% CI 0.84 to 1.72). It also found no significant difference in the number of sores healed at 12 weeks between ultrasound plus UV and laser treatment (6/6 [100%] with ultrasound plus UV *v* 4/6 [67%] with laser treatment; P = 0.2; RR 1.50, 95% CI 0.85 to 2.24). However it was underpowered to find clinically important differences between groups. [59]

Harms: The RCTs identified by the review gave no information on adverse effects. [59]

Comment: None.

OPTION TOPICAL NEGATIVE PRESSURE TO TREAT PRESSURE ULCERS

Healing rates
Compared with control We don't know whether topical negative pressure is more effective at increasing pressure-ulcer healing rates (very low-quality evidence).

For GRADE evaluation of interventions for pressure ulcers, see table, p 22 .

Benefits: We found two systematic reviews (search date 2000, [60] search date 2004 [54]), which between them identified six RCTs — two RCTs in people with pressure ulcers (50 people) and four RCTs in people with any type of wound including pressure ulcers (78 people). All RCTs had weak methods, including reporting of surrogate outcomes and differences in baseline wound severity between groups. Although two RCTs found that topical negative pressure significantly decreased wound volume compared with control, both reviews concluded that, because of trial weaknesses, there was no clear evidence of improved pressure-ulcer healing with topical negative pressure compared with no topical negative pressure.

Harms: The reviews found no increase in adverse effects associated with topical negative pressure. [54] [60]

Comment: None.

OPTION TOPICAL PHENYTOIN TO TREAT PRESSURE ULCERS

Healing rates
*Compared with hydrocolloid/standard dressings or antibiotic ointmen*t We don't know whether topical phenytoin ointment is more effective at increasing pressure-ulcer healing rates (very low-quality evidence).

For GRADE evaluation of interventions for pressure ulcers, see table, p 22 .

Benefits: We found two RCTs. [36] [61] The first RCT (48 people) compared topical phenytoin suspension (100 mg capsule in 5 mL saline) versus hydrocolloid dressings or antibiotic ointment as a treatment for partial-thickness pressure ulcers. [61] It found that topical phenytoin significantly increased the healing rate compared with hydrocolloid dressings or antibiotic ointment (mean time to healing: 35.3 days with topical phenytoin *v* 51.8 days with hydrocolloid dressing *v* 53.8 days with antibiotic

ointment; P less than 0.005 for topical phenytoin *v* either hydrocolloid dressing or antibiotic ointment), but no data that showed baseline equivalence for wound size were presented. The second RCT compared topical phenytoin versus hydrocolloid dressings versus standard dressings. [36] It found that significantly fewer people had complete ulcer healing with phenytoin than with hydrocolloid dressings (3-arm RCT, 83 people; AR for complete ulcer healing: 11/28 [39%] with topical phenytoin *v* 20/28 [71%] with hydrocolloid dressings; ARR 32%, 95% CI 7.4% to 56.7%). More people had complete ulcer healing with phenytoin than with standard dressings, but the significance of this difference was not reported (AR for complete ulcer healing: 11/28 [39%] with topical phenytoin *v* 8/27 [30%] with standard dressings; significance assessment not performed). However, in this second RCT there were important between-group differences at baseline for ulcer size (mean size: 5 cm^2 with topical phenytoin *v* 7 cm^2 with hydrocolloid dressings *v* 10 cm^2 with standard dressings; P greater than 0.10). [36] Although these difference were not significant, they are likely to have biased the results against standard dressings.

Harms: Both RCTs reported no adverse effects associated with topical phenytoin, but were likely to have been underpowered to detect clinically important adverse effects. [36] [61]

Comment: **Clinical guide:**
Topical phenytoin is an experimental treatment rarely used in current clinical practice.

GLOSSARY

Dextranomer paste Anhydrous, porous beads 0.1–0.3 mm in diameter. These beads are hydrophilic and absorb and adsorb exudate, wound debris, and bacteria, depending on particle size.
Air-fluidised supports Membranes that cover a layer of particles that are fluidised by having air forced through them. The airflow can be turned off, which makes the surface solid again, to allow the person to be moved. People find it difficult to get in and out of these beds independently; therefore, they are usually reserved for people who spend most of the day in bed.
Alternating-pressure surfaces Mattresses or overlays made of one or two layers of parallel air sacs. Alternate sacs are inflated and deflated, which provides alternating pressure and release for each area of skin.
Braden Scale Assesses a person's risk of developing a pressure ulcer. It has six subscales: mobility, activity, nutrition, moisture, sensory perception, and friction and shear. The score scale ranges from 6 to 23, with a lower score indicating a greater risk of developing a pressure ulcer.
Electrotherapy The application of electrical fields by placing electrodes near a wound. Treatments include pulsed electromagnetic therapy, low-intensity direct current, negative-polarity and positive-polarity electrotherapy, and alternating-polarity electrotherapy.
Low- or high-tech constant-low-pressure supports Mattresses, overlays, and cushions made of high-density or contoured foam or filled with fibre, gel, water, beads, or air. They increase the area of contact between the person and the support surface and thus reduce the pressure at the interface. See also air-fluidised supports, low-air-loss beds, and low-air-loss hydrotherapy beds.
Low-air-loss beds Mattresses that consist of inflatable upright sacs of semipermeable fabric. Inflation of the sacs increases the area of contact between the individual and the support surface and reduces the pressure on the skin. People find it difficult to get in and out of these beds independently; therefore, they are usually reserved for people who spend most of the day in bed.
Low-air-loss hydrotherapy beds A mattress that consists of cushions covered by a permeable, fast-drying filter sheet, through which air is circulated. The bed also contains a urine-collecting device.
Low-level laser therapy Also known as low-intensity or low-power therapy. It is thought to work by inducing a photochemical response to laser light, which results in biochemical alterations in cells and physiological changes.
Low-quality evidence Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Moderate-quality evidence Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Therapeutic ultrasound The application of ultrasound to a wound with a transducer and water-based gel. The power of ultrasound waves used in wound healing is low to avoid heating the tissues.
Topical negative pressure Negative pressure (suction) applied to a wound through an open-cell dressing (e.g. foam or felt).
Very low-quality evidence Any estimate of effect is very uncertain.

SUBSTANTIVE CHANGES

Alternating pressure surfaces to prevent pressure ulcers One systematic review added; [8] categorisation unchanged (Unknown effectiveness).
Dressings other than hydrocolloid to treat pressure ulcers One small RCT added (reported in two publications); [47] [46] categorisation unchanged (Unknown effectiveness) as there were insufficient people with pressure ulcers in the RCT to draw conclusions.
Electric profiling beds to prevent pressure ulcers One systematic review added; [8] categorisation unchanged (Unknown effectiveness).

Foam alternatives versus standard foam mattresses One systematic review added; [8] categorisation unchanged (Beneficial).
Limb protectors (hydrocellular heel supports) to prevent pressure ulcers One systematic review added; [8] categorisation unchanged (Unknown effectiveness).
Low-air-loss beds to prevent pressure ulcers One systematic review added; [8] categorisation unchanged (Likely to be beneficial).
Low-tech constant low pressure supports to prevent pressure ulcers One systematic review added; [8] categorisation unchanged (Unknown effectiveness).
Nutritional supplements to prevent pressure ulcers One systematic review added; [8] categorisation unchanged (Unknown effectiveness).
Nutritional supplements to treat pressure ulcers One RCT added; [57] categorisation unchanged (Unknown effectiveness).
Repositioning (including regular "turning") to prevent pressure ulcers One systematic review added; [8] categorisation unchanged (Unknown effectiveness).
Seat cushions to prevent pressure ulcers One systematic review added; [8] categorisation unchanged (Unknown effectiveness).
Therapeutic ultrasound One updated systematic review added; [59] categorisation unchanged (Unknown effectiveness).
Topical lotions and dressings to prevent pressure ulcers One systematic review added; [8] categorisation unchanged (Unknown effectiveness).
Limb protectors (air-filled vinyl boots) to prevent pressure ulcers One systematic review added; [8] evidence reassessed. Categorisation changed from Likely to be ineffective or harmful to Unlikely to be beneficial.
Low-air-loss hydrotherapy beds to prevent pressure ulcers One systematic review added; [8] evidence reassessed. Categorisation changed from Likely to be ineffective or harmful to Unlikely to be beneficial.
Pressure-relieving overlays on operating tables One systematic review added, [8] which identified RCTs that reported opposing results to those previously reported by an earlier review — in fact, suggesting that overlays may increase pressure ulcers. [7] The effects of pressure-relieving overlays are now unclear; categorisation changed from Beneficial to Unknown effectiveness.

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Disclaimer

TABLE 1 **RCTs of debridement for pressure sores, published subsequent to systematic review.** [28]

Reference	Population	Interventions	Results
[29]	23 people with 30 ulcers	Dextranomer paste *v* saline soaked gauze	No significant difference in the proportion of sores ready for skin grafting within 15 days (5/15 [33%] with dextranomer paste *v* 4/15 [27%] with saline; ARI +7%, 95% CI –26% to +38%)
[30]	43 people	Collagenase *v* hydrocolloid dressings	No significant difference in healing (3 people in each group healed; no denominator reported).
[31]	24 women with full-thickness heel sores	Collagenase *v* hydrocolloid dressings	Sores treated with collagenase healed significantly more quickly, but results may be confounded by baseline differences in wound size (data not reported)
[32]	21 people	Papain plus urea *v* collagenase	No significant difference in healing rates over 4 weeks (reduction in ulcer size: 55% with papain plus urea *v* 34% with collagenase; reported as not significant, P value not reported)
[33]	135 people	Collagenase *v* fibrinolysin plus deoxyribonuclease	No significant difference in healing at 4 weeks (decrease at least 25% in necrotic wound area: 37/60 [62%] with collagenase *v* 35/61 [57%] with fibrinolysin plus deoxyribonuclease; P = 0.115 across 5 classifications of wound change)

TABLE **GRADE evaluation of interventions for pressure ulcers**

Important outcomes	Incidence of pressure ulcers, symptom severity, time to heal								
Number of studies (participants)	**Outcome**	**Comparison**	**Type of evidence**	**Quality**	**Consistency**	**Directness**	**Effect size**	**GRADE**	**Comment**
What are the effects of preventive interventions in people at risk of developing pressure ulcers?									
6 (2117) [7]	Incidence of pressure ulcers	Foam alternatives *v* standard hospital mattresses	4	–2	0	0	0	Low	Quality points deducted for incomplete reporting of results and poor-quality RCTs
1 (40) [7]	Incidence of pressure ulcers	Foam alternatives compared with each other	4	–3	0	0	+1	Low	Quality points deducted for sparse data, incomplete reporting of results, and poor-quality RCTs. Effect-size point added for RR less than 0.5
5 (1402) [7] [8] [9]	Incidence of pressure ulcers	Pressure-relieving overlays on operating tables *v* standard table alone	4	–2	–1	0	0	Very low	Quality points deducted for incomplete reporting of results and poor-quality RCTs. Consistency point deducted for conflicting results
2 (160) [7] [10]	Incidence of pressure ulcers	Low-air-loss beds *v* standard intensive care beds/alternating pressure mattresses	4	–2	–1	0	0	Very low	Quality points deducted for sparse data and incomplete reporting of results. Consistency point deducted for conflicting results
2 (748) [7] [11]	Incidence of pressure ulcers	Medical sheepskin overlays *v* standard care	4	–1	0	0	0	Moderate	Quality point deducted for no intention-to-treat analysis
2 (435) [7] [12]	Incidence of pressure ulcers	Alternating pressure surfaces *v* standard foam mattress	4	–3	0	0	0	Very low	Quality points deducted for incomplete reporting of results, no intention-to-treat analysis, poor follow-up, and poor-quality RCTs
9 (1466) [7] [13]	Incidence of pressure ulcers	Alternating pressure surfaces *v* constant low pressure supports	4	–3	0	0	0	Very low	Quality points deducted for incomplete reporting of results, uncertainty about follow-up, and poor-quality RCTs
2 (2153) [7] [15] [16]	Incidence of pressure ulcers	Alternating pressure surfaces *v* each other	4	–2	0	0	0	Low	Quality points deducted for incomplete reporting of results and poor-quality RCTs
4 (473) [7] [17]	Incidence of pressure ulcers	Seat cushions *v* each other	4	–1	0	0	0	Moderate	Quality point deducted for incomplete reporting of results
1 (70) [7]	Incidence of pressure ulcers	Electric profiling beds *v* standard hospital beds	4	–2	0	0	0	Low	Quality points deducted for sparse data and incomplete reporting of results
7 (1451) [7] [8]	Incidence of pressure ulcers	Low-tech constant low pressure supports *v* other pressure-relieving devices	4	–2	0	–1	0	Very low	Quality points deducted for incomplete reporting of results and poor-quality RCTs. Directness point deducted for uncertainty about benefit
5 (1475) [18] [8] [19]	Incidence of pressure ulcers	Nutritional supplements *v* control/standard care	4	–3	0	–1	0	Very low	Quality points deducted for incomplete reporting of results and for methodological flaws. Directness point deducted for baseline differences between groups
4 (1055) [20] [22]	Incidence of pressure ulcers	Repositioning (including regular turning) *v* standard care	4	–2	0	0	0	Low	Quality points deducted for incomplete reporting of results, poor-quality RCTs, and methodological flaws
1 (807) [21] [22]	Incidence of pressure ulcers	Repositioning at 30 ° tilt *v* a 90 ° lateral and supine position	4	–1	0	–1	0	Low	Quality point deducted for sparse data. Directness point deducted for uncertainty about benefit
3 (618) [23] [24]	Incidence of pressure ulcers	Topical lotions *v* topical placebo/other lotions	4	–2	–1	0	0	Very low	Quality points deducted for incomplete reporting of results and no intention-to-treat analysis. Consistency point deducted for conflicting results

Important outcomes	Incidence of pressure ulcers, symptom severity, time to heal								
Number of studies (participants)	Outcome	Comparison	Type of evidence	Quality	Consistency	Directness	Effect size	GRADE	Comment
1 (52) [7] [8]	Incidence of pressure ulcers	Air-filled vinyl boots *v* hospital pillows	4	–1	0	0	0	Moderate	Quality point deducted for sparse data
1 (111) [25]	Incidence of pressure ulcers	Hydrocellular heel supports *v* orthopaedic wool padding	4	–2	0	0	0	Low	Quality points deducted for sparse data and no intention-to-treat analysis
1 (98) [7] [8]	Incidence of pressure ulcers	Low-air-loss hydrotherapy beds *v* support surfaces	4	–1	0	0	0	Moderate	Quality point deducted for sparse data
What are the effects of treatments in people with pressure ulcers?									
3 (202) [26]	Healing rates	Air-fluidised support *v* standard care	4	–2	–1	–1	0	Very low	Quality points deducted for incomplete reporting of results and no intention-to-treat analysis. Consistency point deducted for conflicting results. Directness point deducted for uncertainty about generalisability of benefits
4 (372) [26] [27]	Healing rates	Alternating pressure surfaces *v* each other/standard care	4	–1	0	0	0	Moderate	Quality point deducted for incomplete reporting of results
5 (246) [29] [30] [31] [32] [33]	Healing rates	Debriding agents *v* each other	4	–1	0	–2	0	Very low	Quality point deducted for incomplete reporting of results. Directness points deducted for inclusion of range of wounds and for uncertainty about relative effectiveness of agents
8 (at least 472 wounds) [34] [35] [37] [38] [36]	Healing rates	Hydrocolloid dressings *v* gauze soaked in saline, hypochloride, or povidone iodine	4	–2	–1	–1	0	Very low	Quality points deducted for incomplete reporting of results and inclusion of poor-quality RCTs. Consistency point deducted for conflicting results. Directness point deducted for baseline differences in ulcer sizes between groups
1 (110) [39]	Healing rates	Hydrocolloid dressings *v* other dressings	4	–1	0	0	0	Moderate	Quality point deducted for sparse data
3 (135) [45] [48] [47] [46]	Healing rates	Dressings other than hydrocolloids *v* each other	4	–2	–1	0	0	Very low	Quality points deducted for sparse data and incomplete reporting of results. Consistency point deducted for different results for different dressings
4 (at least 112 people) [26] [50] [49]	Healing rates	Electrotherapy *v* sham electrotherapy	4	–2	–1	0	0	Very low	Quality points deducted for incomplete reporting of results and inclusion of poor-methodology RCTs. Consistency point deducted for conflicting results
2 (133) [26]	Healing rates	Low-air-loss beds *v* convoluted foam	4	–2	0	0	0	Low	Quality points deducted for sparse data and incomplete reporting of results
4 (200) [53] [55]	Healing rates	Laser treatment *v* standard care/sham treatment	4	–3	–1	0	0	Very low	Quality points deducted for poor-quality RCTs, incomplete reporting of results, no intention-to-treat analysis, and poor and short follow-up. Consistency point deducted for conflicting results
1 (120) [26]	Healing rates	Low-tech constant low pressure supports *v* each other	4	–2	0	0	0	Low	Quality points deducted for sparse data and incomplete reporting of results
5 (225) [18] [56] [57]	Healing rates	Nutritional supplements *v* control (low dose or no supplements)	4	–2	–1	0	0	Very low	Quality points deducted for poor methodologies (randomisation flaws, no intention-to-treat analysis, poor follow-up). Consistency point deducted for conflicting results

Important outcomes	Incidence of pressure ulcers, symptom severity, time to heal								
Number of studies (participants)	Outcome	Comparison	Type of evidence	Quality	Consistency	Directness	Effect size	GRADE	Comment
2 (235) [26] [58]	Healing rates	Seat cushions compared with each other	4	–3	–1	0	0	Very low	Quality points deducted for incomplete reporting of results and methodological flaws. Consistency point deducted for conflicting results
2 (128) [59]	Healing rates	Ultrasound *v* sham ultrasound	4	–3	0	0	0	Low	Quality points deducted for sparse data and incomplete reporting of results
1 (12) [59]	Healing rates	Ultrasound plus ultraviolet *v* standard care *v* laser treatment	4	–1	0	0	0	Moderate	Quality point deducted for sparse data
6 (128) [54] [60]	Healing rates	Topical negative pressure *v* control	4	–3	0	–1	0	Very low	Quality points deducted for sparse data, incomplete reporting of results, and weak methodologies. Directness points deducted for baseline differences in wound severity
2 (131) [36] [61]	Healing rates	Topical phenytoin *v* hydrocolloid or standard dressings/antibiotic ointment	4	–1	–1	–1	0	Very low	Quality point deducted for sparse data. Consistency point deducted for conflicting results. Directness points deducted for baseline differences in ulcer sizes

Type of evidence: 4 = RCT; 2 = Observational; 1 = Non-analytical/expert opinion. Consistency: similarity of results across studies
Directness: generalisability of population or outcomes
Effect size: based on relative risk or odds ratio